IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPLICANT:	Takeda Pharmaceutical Co., Ltd.
U.S. PATENT NO.	6,939,971
ISSUED:	September 6, 2005
TO:	FUJISHIMA ET AL.
FOR:	BENZIMIDAZOLE COMPOUND CRYSTAL
FROM:	Serial No. 10/655114
FILED:	September 4, 2003
EXTENSION FILED:	March 26, 2009
ATTORNEY DOCKET NO.	04164.0013USTE

DATE: April 29, 2010

CERTIFICATE UNDER 37 CFR 1.10:
I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, with sufficient postage, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on April 29, 2010.

By: Linda Binion
Name: Linda Binion

SUBMISSION OF SUPPLEMENTAL APPLICATION FOR EXTENSION OF PATENT TERM UNDER 35 U.S.C. §156 TO APPLICATION FILED ON MARCH 26, 2009

Mail Stop: Patent Extension
Commissioner of Patents
Patent Extension
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Applicant Takeda Pharmaceutical Company Limited hereby submits this supplemental application for extension of patent term for the above identified patent due to a change of the name of the Approved Product from "Kapidex" to "Dexilant" in April 2010. The actual product has not been changed.

Takeda Pharmaceutical Company Limited ("Takeda" or "Applicant"), a corporation organized and existing under the laws of Japan, having its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka-shi, Osaka, Japan, represents that it is the owner and assignee of the entire interest in and to the above-identified patent. Applicant was formerly called Takeda Chemical Industries Limited, which was the original assignee of U.S. Patent No. 6,939,971, and changed its name to Takeda Pharmaceutical Company Limited as of June 29, 2004. Based on this change of the corporate name, the change of name of the assignee of the above-identified patent to Applicant was recorded on June 2, 2005. A copy of the assignment of U.S. Patent No. 6,939,971 to Takeda Chemical Industries Limited (Exhibit A) and a copy of the documents filed for the change of the corporate name to Takeda Pharmaceutical Company Limited (Exhibit B) are attached hereto.

The NDA application of the Approved Product for the regulatory review by the United States Food and Drug Administration ("FDA") was filed by TAP Pharmaceutical Products Inc., which had been a 50-50 joint venture corporation between Takeda Pharmaceutical Co., Ltd. and Abbott Laboratories and had been a licensee of Applicant for the Approved Product. TAP Pharmaceutical Products Inc. was merged with Takeda Pharmaceuticals North America, Inc. and Takeda Global Research & Development Center, Inc. as of July 1, 2008 and accordingly, Takeda Pharmaceuticals North America, Inc., which is a subsidiary of Applicant, is the owner of the NDA approval of the Approval Product. A copy of the NDA approval is attached hereto as Exhibit C.

Applicant hereby petitions for extension of U.S. Patent No. 6,939,971under 35 U.S.C. §156(d) and 37 C.F.R. §1.740 and states in part thereof as follows:

(1) A COMPLETE IDENTIFICATION OF THE APPROVED PRODUCT AS BY APPROPRIATE CHEMICAL AND GENERIC NAME, PHYSICAL STRUCTURE OR CHARACTERISTICS

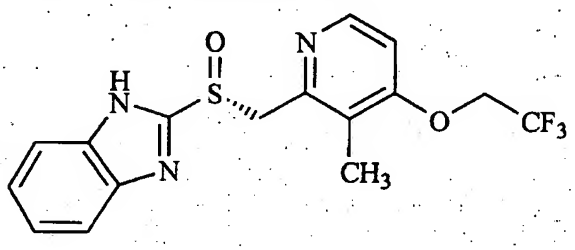
The name of the Approved Product "Kapidex" in the above identified application submitted on March 26, 2009 has been changed to "Dexilant" since April 2010.

The chemical and generic name, physical structure, or characteristics of a new drug Dexilant (hereinafter sometimes referred to as "Approved Product"), which is approved by the FDA, are as follows:

The generic name of the active ingredient contained in the Approved Product is dexlansoprazole.

The chemical name of dexlansoprazole is:
2-[(R)-[[3-methyl-4-(2,2,2-trifluoroethoxy)-2-pyridyl]methyl]sulfinyl]-1H-benzimidazole.

The chemical structure of dexlansoprazole is:



with a molecular formula of $C_{16}H_{14}F_3N_3O_2S$ and a molecular weight of 369.36 (based on the 2001 International Union of Pure and Applied Chemistry [IUPAC] Atomic Weight of the Elements). The Approved Product Dexilant includes a crystal form of dexlansoprazole. The data of Dexilant in the NDA submitted to the FDA were produced by using the same crystalline form of dexlansoprazole as that of claim 1 in U.S. Patent No. 6,939,971.

(2) A COMPLETE IDENTIFICATION OF THE FEDERAL STATUTE INCLUDING THE APPLICABLE PROVISION OF LAW UNDER WHICH THE REGULATORY REVIEW OCCURRED

An application for commercial marketing approval of Dexilant in the U.S. was filed pursuant to §505 (b) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (21 U.S.C. §355(b)) and reviewed under this section of the law.

(3) AN IDENTIFICATION OF THE DATE ON WHICH THE PRODUCT RECEIVED PERMISSION FOR COMMERCIAL MARKETING OR USE UNDER THE PROVISION OF LAW UNDER WHICH THE APPLICABLE REGULATORY REVIEW PERIOD OCCURRED

The commercial marketing of the Approved Product was approved on January 30, 2009 by the FDA. A copy of the FDA approval is attached hereto as Exhibit C.

(4) IN THE CASE OF A DRUG PRODUCT, AN IDENTIFICATION OF EACH ACTIVE INGREDIENT IN THE PRODUCT AND AS TO EACH ACTIVE INGREDIENT, A STATEMENT THAT IT HAS NOT BEEN PREVIOUSLY APPROVED FOR COMMERCIAL MARKETING OR USE UNDER THE FDCA, THE PUBLIC HEALTH SERVICE ACT, OR THE VIRUS-SERUM-TOXIN ACT, OR A STATEMENT OF WHEN THE ACTIVE INGREDIENT WAS APPROVED FOR COMMERCIAL MARKETING OR USE (EITHER ALONE OR IN COMBINATION WITH OTHER ACTIVE INGREDIENTS), THE USE FOR WHICH IT WAS APPROVED, AND THE PROVISION OF LAW UNDER WHICH IT WAS APPROVED

The Approved Product Dexilant is a sustained release formulation in a capsule using a crystalline form of dexlansoprazole as an active ingredient. This active ingredient has not been approved previously for the commercial marketing or use under the FDCA, the Public Health service Act, or the Virus-Serum-Toxin Act. Lansoprazole, a racemate of the active ingredient of the Approved Product, has been approved previously.

(5) A STATEMENT THAT THE APPLICATION IS BEING SUBMITTED WITHIN THE SIXTY DAY PERIOD PERMITTED FOR SUBMISSION PURSUANT TO § 1.720(f) AND AN IDENTIFICATION OF THE DATE OF THE LAST DAY ON WHICH THE APPLICATION COULD BE SUBMITTED

The sixty (60)-day period began on the approval date of the Approved Product January 30, 2009 and will expire on March 30, 2009. Accordingly, this application is being submitted within the 60-day period pursuant to 37 C.F.R. §1.720(f).

(6) A COMPLETE IDENTIFICATION OF THE PATENT FOR WHICH AN EXTENSION IS BEING SOUGHT BY THE NAME OF THE INVENTOR, THE PATENT NUMBER, THE DATE OF ISSUE, AND THE DATE OF EXPIRATION

The information of patent for which this application is submitted is as follows:

U.S. Patent No.:	6,939,971
Inventors:	Akira Fujishima
	Isao Aoki

	Keiji Kamiyama
Title:	BENZIMIDAZOLE COMPOUND CRYSTAL
Date of issue:	September 6, 2005
Date of expiration:	June 15, 2020 absent the extension

U.S. Patent No. 6,939,971 was granted on the 6th day of September 2005 to Akira Fujishima, Isao Aoki, and Kenji Kamiyama and was assigned to Takeda Chemical Industries Ltd. Takeda Chemical Industries Ltd. changed the corporate name to Takeda Pharmaceutical Co., Ltd. as of June 29, 2004, and the name change to Takeda Pharmaceutical Co. Ltd. was recorded in the United Patent Trademark Office on June 2, 2005, at Reel 018917, Frame 0406. The June 29, 2004 execution date of the name change was erroneously recorded in the assignment record of the USPTO as October 13, 2004, on which the Osaka Chamber of Commerce & Industry issued the certificate of membership of Applicant. A copy of the assignment to Takeda Chemical Industries Ltd. and the change of the corporate name are attached hereto as Exhibits A and B, respectively.

(7) A COPY OF THE PATENT FOR WHICH AN EXTENSION IS BEING SOUGHT, INCLUDING THE ENTIRE SPECIFICATION (INCLUDING CLAIMS) AND DRAWINGS

A copy of the U.S. Patent No. 6,939,971, for which the extension is being sought, including the entire specification (including claims) is attached hereto as Exhibit D.

(8) A COPY OF DISCLAIMER, CERTIFICATE OF CORRECTION, RECEIPT OF MAINTENANCE FEE PAYMENT, OR REEXAMINATION CERTIFICATE ISSUED IN THE PATENT

U.S. Patent No. 6,939,971, for which this application of the patent term extension is filed, is presently subject to terminal disclaimers over U.S. Patent Nos. 6,462,058 and 6,664,276 as shown in Exhibits E and F, respectively, attached hereto. U.S. Patent No. 6,462,058 will expire on June 15, 2020, 20 years from the June 15, 2000 international filing date. U.S. Patent No. 6,664,276 (Application No. 10/243329) is subject to terminal disclaimers over U.S. Patent No. 6,462,058 and U.S. Patent No. 6,608,092 (Application No. 10/019254) (see Exhibits G and H, respectively), which is also subject to a terminal

disclaimer over U.S. Patent No. 6,462,058 and U.S. Patent No. 6,664,276, and is scheduled to expire on June 15, 2020. Thus, U.S. Patent No. 6,664,276 is scheduled to expire on June 15, 2020.

Because of the terminal disclaimers, U.S. Patent No. 6,939,971 is currently scheduled to expire on June 15, 2020.

No certificate of correction or reexamination certificate has been issued.

A copy of documents showing payment of the maintenance fee payment for U.S. Patent No. 6,939,971 is attached hereto as Exhibit I.

(9) A STATEMENT THAT THE PATENT CLAIMS THE APPROVED PRODUCT, OR A METHOD OF USING OR MANUFACTURING THE APPROVED PRODUCT, AND A SHOWING WHICH LISTS EACH APPLICABLE PATENT CLAIM AND DEMONSTRATES THE MANNER IN WHICH AT LEAST ONE SUCH PATENT CLAIM READS

U.S. Patent No. 6,939,971 claims a method of using a pharmaceutical composition of a crystalline form of dexlansoprazole, which is an active ingredient of the Approved Product, for an intended use in claims 1 and 2, a method of using the Approved Product having a particular crystalline form of dexlansoprazole for the intended use in claim 3, a method of using the Approved Product for an approved indication in claims 5 and 6, a method of using of the Approved Product, in which dexlansoprazole has the particular crystalline form, for the approved indication in claim 7, a method of using the Approved Product for another intended use in claims 9 and 15, and a method of using the Approved Product, in which dexlansoprazole has the particular crystalline form, for the other intended use in claim 16 as shown in Exhibit J. The claimed particular crystalline form in claims 3, 7, and 16 is the same crystalline form as that used for the NDA of the Approved Product (see Exhibit K). Please note that the X-ray powder diffraction of dexlansoprazole in the Approved Product was measured by different equipment under different measuring conditions from those used to obtain data for U.S. Patent No. 6,939,971 and might include minor experimental deviations.

(10) A STATEMENT OF THE RELEVANT DATES AND INFORMATION PURSUANT TO 35 U.S.C. 156(G) IN ORDER TO ENABLE THE SECRETARY OF HEALTH AND HUMAN SERVICES OR THE SECRETARY OF AGRICULTURE, AS APPROPRIATE, TO DETERMINE THE APPLICABLE REGULATORY REVIEW PERIOD

The information required by 37 C.F.R. §1.740(a)(10) for a patent claiming the Approved Product, a human drug Dexilant, is as follows:

(A) Effective date of the investigational new drug (IND) application and the IND number:

Effective date of IND Application: July 2, 2004

IND number: 69,927

(B) Effective date on which a new drug application (NDA) was initially filed and the NDA number:

Application date of NDA: December 28, 2007

NDA number: 22-287

(C) Date on which the NDA No. 22-287 was approved is January 30, 2009.

(11) **A BRIEF DESCRIPTION OF THE SIGNIFICANT ACTIVITIES UNDERTAKEN BY THE MARKETING APPLICANT DURING THE APPLICABLE REGULATORY REVIEW PERIOD WITH RESPECT TO THE APPROVED PRODUCT AND THE SIGNIFICANT DATES APPLICABLE TO SUCH ACTIVITIES**

A brief description of the significant activities undertaken by the applicant of the commercial marketing approval Takeda during the applicable regulatory period for the Approved Product and the significant dates applicable to such activities are shown in Exhibit L attached hereto.

(12) A STATEMENT THAT IN THE OPINION OF THE APPLICANT THE PATENT IS ELIGIBLE FOR THE EXTENSION AND A STATEMENT AS TO THE LENGTH OF EXTENSION CLAIMED, INCLUDING HOW THE LENGTH OF EXTENSION WAS DETERMINED

Applicant is of the opinion that U.S. Patent No. 6,939,971 is eligible for the patent term extension under 35 U.S.C. §156 because the requirements of 35 U.S.C. §156 (a) and (c)(4) have been satisfied as follows:

(a) 35 U.S.C. §156(a)

U.S. Patent No. 6,939,971 claims a method of using a crystalline form of dexlansoprazole, which is an active ingredient of a human drug Dexilant, i.e., the Approved Product, as defined in 37 C.F.R. §1.710, in claims 1-3, 5-7, and 9-16 including a method of treatment of reflux esophagitis, which is an approved indication for the Approved Product (claims 5-7), and a particular crystalline form of dexlansoprazole used for the data filed for the NDA of the Approved Product is claimed in claims 3, 7, and 16.

(b) 35 U.S.C. §156(a)(1)

U.S. Patent No. 6,939,971 has not yet expired as of the date of submission of this application.

(c) 35 U.S.C. §156(a)(2)

The term of U.S. Patent No. 6,939,971 has never been extended under 35 U.S.C. §156(e)(1).

(d) 35 U.S.C. §156(a)(3)

This application for extension of U.S. Patent No. 6,939,971 is being submitted by the owner of record Takeda Pharmaceutical Co., Ltd. through their attorneys in accordance with the requirements of 35 U.S.C. §156(d)(1) through (4).

(e) 35 U.S.C. §156(a)(4)

The Approved Product Dexilant has been subject to a regulatory review period under §505 of the FDCA (21 U.S.C. §355) before its commercial marketing or use.

(f) 35 U.S.C. §156(a)(5)(A)

The permission for the commercial marketing or use of the Approved Product after such regulatory review period is the first permitted commercial marketing or use of the Approved Product and the active ingredient of the Approved Product dexlansoprazole under §505 of the FDCA (21 U.S.C. §355).

(g) 35 U.S.C. §156(c)(4)

To the date of this application, there is no other U.S. patent that has been extended under 35 U.S.C. §156(e)(1) for the same regulatory review period for the Approved Product. Applicant acknowledges that applications for extension of U.S. Patent Nos. 6,462,058 and 6,664,276 are being filed based on the same regulatory review period, and confirms that Applicant will elect one of the three for grant.

Applicant further is of the opinion that U.S. Patent No. 6,939,971 is entitled to the patent term extension under 35 U.S.C. §156 for the length of 822 days extended from June 15, 2020 as determined pursuant to 37 C.F.R. §1.775 by the following:

(a) 37 C.F.R. §1.775(b)

The number of days in the period beginning on the effective date of the IND application for the Approved Product July 2, 2004 and ending on December 28, 2007, which is the date of the initial NDA application for the Approved Product was filed under §505(b) of the FDCA, is 1275 days ("Period (c)-1" as defined under 35 U.S.C. §156(g)(1)(B)(i)).

The number of days in the period beginning on the date of the NDA application for the Approved Product December 28, 2007 and ending on the approval date of the NDA January 30, 2009 is 400 days ("Period (c)-2" as defined under 35 U.S.C. §156(g)(1)(B)(ii)).

(b) 37 C.F.R. §1.775(d)(1)

The term of extension of U.S. Patent No. 6,939,971 is determined by subtracting the number of days of (i)-(iii) below from the total period of Period (c)-1 and Period (c)-2.

(i) The number of days in Periods (c)-1 and (c)-2 on and before the issue date of U.S. Patent No. 6,939,971 September 6, 2005 is 432 days.

(ii) The number of days in Period (c)-1 and (c)-2 during which Applicant did not act with due diligence is zero (0) day.

(iii) One-half (1/2) the number of days remaining in the Period (c)-1 after reduced by the days of (b)-(i) and (ii) above is 421 days (1/2 x (1275-432) days ignoring a half day).

Accordingly, the extension period is 822 days, calculated by subtracting 853 days (432 + 421 days) from 1675 days (Periods (c)-1 and (c)-2: 1275 + 400 days).

(c) 37 C.F.R. §1.775(d)(2)

U.S. Patent No. 6,939,971 filed on September 4, 2003 is subject to the terminal disclaimer filed for U.S. Patent No. 6,664,276, and the current expiration date of the '971 patent is scheduled on June 15, 2020, 20 years from the Jun 15, 2000 international filing date of the parent '058 patent for which a terminal disclaimer of the patent '276 has been filed. The extended expiration date of U.S. Patent No. 6,939,971 obtained by adding 822 days to June 15, 2020 is September 15, 2022.

(d) 37 C.F.R. §1.775(d)(3)

The extended date calculated by adding 14 years to the NDA approval date January 30, 2009 is January 30, 2023.

(e) 37 C.F.R. §1.775(d)(4)

The earlier date of the extended expiration dates of U.S. Patent No. 6,939,971 in (c) and (d) above is September 15, 2022.

(f) 37 C.F.R. §1.775(d)(5)

The earlier date of the extended expiration dates of U.S. Patent No. 6,939,971 in (e) and the date June 15, 2025 calculated by adding five (5) years to the current expiration date June 15, 2020 is September 15, 2022.

In light of the (a)-(e) above, Applicant is in the opinion that the extended expiration date of U.S. Patent No. 6,939,971 should be September 15, 2022, i.e., 822 days or 2 years and 92 days from the date of the current expiration date June 15, 2020.

(13) A STATEMENT THAT APPLICANT ACKNOWLEDGES A DUTY TO DISCLOSE TO THE DIRECTOR OF THE UNITED STATES PATENT AND TRADEMARK OFFICE AND THE SECRETARY OF HEALTH AND HUMAN SERVICES ANY INFORMATION WHICH IS MATERIAL TO THE DETERMINATION OF ENTITLEMENT TO THE EXTENSION SOUGHT

Applicant acknowledges a duty to disclose to the Commissioner of Patents and Trademarks and to the Secretary of Health and Human Services any information that is material to the determination of entitlement to the extension of U.S. Patent No. 6,939,971 being sought.

(14) THE PRESCRIBED FEE FOR RECEIVING AND ACTING UPON THE APPLICATION FOR EXTENSION

The filing fee of the application for extension was paid upon filing the original application on March 26, 2009. Please charge any additional fees or credit overpayment to Deposit Account No. 50-3478.

(15) THE NAME, ADDRESS, AND TELEPHONE NUMBER OF THE PERSON TO WHOM INQUIRIES AND CORRESPONDENCE RELATING TO THE APPLICATION FOR PATENT TERM EXTENSION ARE TO BE DIRECTED

Please address all inquires and correspondence relating to this application for patent term extension to:

Douglas P. Mueller
HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

(16) **THE APPLICATION UNDER THIS SECTION MUST BE ACCOMPANIED BY TWO ADDITIONAL COPIES OF SUCH APPLICATION**

No additional copies of this supplemental application are attached hereto as instructed.

Respectfully submitted,

HAMRE, SCHUMANN, MUELLER & LARSON, P.C.
P.O. Box 2902
Minneapolis, MN 55402-0902
(612) 455-3800

Dated: April 29, 2010

By: _____
Douglas P. Mueller
Reg. No. 30,300

DPM/my